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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/677,375 | 09/15/2000 | Carl-Martin Bell | 65-99 | 2748 |

23713 7590 04/30/2003

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| EXAMINER |
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LUKTON, DAVID

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| ART UNIT | PAPER NUMBER |
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1653

DATE MAILED: 04/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/677,375

Applicant(s)

BELL ET AL.

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 20-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Applicants' election of Group 9 with traverse is acknowledged. Also acknowledged are applicants' species election (arginine and Toyopearl). Applicants have argued that Groups 5, 7 and 9 are "technically linked". Whatever the merits of this argument, however, the claims are not limited to these groups. Applicants have not argued that Groups 4, 6 and 8 are "technically linked". Accordingly, it is reasonable to conclude that Groups 4, 6 and 8 are distinct from one another. As it happens, claims 1-5 encompass Group 4, claims 6-13 encompass Group 6, and claims 14-19 encompass Group 8. Thus, given the claims as currently rendered, the examiners assertion of distinctness remains unchallenged.

Claims 1-13 and 20-26 are withdrawn from consideration.

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Claims 14-19 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites that the ligand can consist of **un**branched peptides only. At the same time, the claim mandates that the peptides be "polydisperse" with respect to number of branches per molecule. Thus, if one has a mixture of unbranched^h peptides, how does one obtain polydispersity with respect to branching?

*

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claim 14 is rejected under 35 U.S.C. §103 as being unpatentable over Colvin (USP 6344360) or Baldo (USP 5061626) in view of applicants' admission.

Colvin discloses (col 14, line 7) polylysine is itself a solid phase support. This is also disclosed in Baldo at col 5, lines 1-3. Both references suggest attaching additional groups to the polylysine. However, this ground of rejection can be considered from the perspective of one who is in possession of the polylysine, irrespective of whether any further modification of that polylysine is undertaken.

Although claim 6 is non-elected, applicants have implied that claim 14 is obvious over

claim 6. If claim 6 were directly at issue, it would be anticipated, or at least rendered obvious, by the references. The requirements of claim 6 are met if a reference discloses peptides (which can be linear) which are bonded to a solid phase support, which peptides contain at least one lysine, and with the further requirement that all such peptides do not have the same molecular weight. All of these requirements are met by a reference which discloses that polylysine is itself a solid phase support. Suppose, for example, that one had a single polylysine polymer which consists of 1000 lysines. In such a case, residues 1-10 (for example) could be one peptide, and residues 991-1000 could be a second peptide. In addition, residues 11-15 could be a third peptide (although two peptides would appear to be sufficient). Thus, if claim 6 were directly at issue, it would be anticipated, or at least rendered obvious. Instead, claim 14 is at issue. However, applicants have implied (paper No. 10, filed 2/12/03) that claim 14 is obvious over claim 6.

It is suggested that applicants do either of the following: (a) assume that claim 14 is an "obvious variant" of claim 6, and amend claim 14 to overcome the references, or (b) admit that claim 14 is distinct from claim 6.

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Claim 14 is rejected under 35 U.S.C. §103 as being unpatentable over Kauvar (USP 5,599,901).

Kauvar discloses (col 8, line 62+) a "family" of peptides which are to be bonded (col 7,

line 39+) to a solid phase support.

If claim 6 were directly at issue, it would be anticipated, or at least rendered obvious, by Kauvar, for the reasons given above. Given applicants view that if claim 6 is rendered obvious by a reference, then claim 14 must be rendered obvious, this ground of rejection is justified.

It is suggested that applicants cancel claims 1-13 and 24-26.

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Claims 14 and 19 are rejected under 35 U.S.C. §103 as being unpatentable over Suzuki (EP 0,028,937) in view of Carter (USP 5,780,594).

Suzuki discloses a device for removing "noxious substances" from blood. The device contains albumin bonded to a solid phase support. Suzuki does not disclose that albumin contains arginine, lysine and histidine. Carter discloses that SEQ ID NO: 3 (cols 9-10) is the sequence of human albumin. Carter does not disclose methods of removing endotoxins from blood.

The limitations of claim 14 are met if a reference discloses peptides (which can be linear) that are bonded to a solid phase support, which peptides contain at least one Lys (or His or Arg), and with the further requirement that all such peptides do not have the same molecular weight. Clearly, albumin contains all three of the requisite amino acids. The issue pertains to the requirement that the peptides do not all have the same molecular weight. As

it happens, claim 14 does not specify the composition of the solid phase support. Suzuki suggests using an epoxy resin. However, there is more to the analysis. Since claim 14 does not specify the composition of the solid phase support, there is nothing to preclude the solid phase support from containing one or more amino acids. Consider the first 15 amino acids of albumin:

DAHKSEVAHRFKDLGE

Let "X" represent a solid phase support consisting of epoxy resin. For the case of albumin bonded to the epoxy resin via the N-terminal amino acid, the resulting immobilized peptide can be depicted as follows: X-DAHKSEVAHRFKDLGE

Thus, one can say that there is a 16-mer peptide bonded to a solid phase support. But there is nothing to preclude the solid phase support from being the following: X-DA.

That is, a solid phase support could be an epoxy resin to which is bonded the dipeptide Asp-Ala. According to this interpretation, the peptide which is bonded to the (unspecified) resin is not DAHKSEVAHRFKDLGE, but is instead HKSEVAHRFKDLGE. Similarly, a solid phase support could be an epoxy resin to which is bonded the tetrapeptide Asp-Ala-His-Lys. According to this interpretation, the peptide which is bonded to the

(unspecified) resin is not DAHKSEVAHRFKDLGE, but is instead SEVAHRFKDLGE.

Thus, significant "polydispersity" with respect to molecular weight is achieved by a semantic "sleight of hand".

Thus, the claims are rendered obvious.

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The documents published in German were stricken from the IDS because of the absence of a translation. With respect to the abstracts, it is suggested that the following be listed on the IDS under the "other prior art" section: **Abstract of DE 19609479.**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


**DAVID LUKTON
PATENT EXAMINER
GROUP 1800**